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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,724

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Mauro Marzi

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2529

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EXAMINER

AULAKH, CHARANJIT

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 05/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/511,724

Applicant(s)

MARZI ET AL.

Examiner

Charanjit S. Aulakh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 13 and 15-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 13 and 15-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. According to paper filed on March 3, 2006, the applicants have canceled claims 10-12 and 14; amended claims 1-9, 13 and 15-18 and furthermore, have added new claim 19.
2. Claims 1-9, 13 and 15-19 are now pending in the application.

Response to Arguments

3. Applicant's arguments filed on March 3, 2006 have been fully considered but they are not persuasive regarding enablement rejection, some indefiniteness rejections, prior art rejections and obviousness rejections. In regard to enablement rejection, the examiner does not agree with the applicants arguments that the specification is enabling for treating every known tumor and every known viral and parasitic infections by the instant compounds of formulae (I) and (II). The applicants argue that Camptothecins are well known compounds and their antitumor activity is well known in the art. However, the instant compounds are not Camptothecins. They are structurally different from the known camptothecins since the instant compounds have either a 5-membered or a 7-8 membered lactone ring instead of a 6-membered lactone ring. There is no teaching either in the specification or prior art regarding treating every known tumor, viral and parasitic diseases with pentacyclic compounds having either a 5-membered lactone ring or a 7-8-membered lactone ring. In regard to indefiniteness rejections, the applicants did not amend claim 9 to delete the term --envisaged ---in step b. The examiner also does not agree with the applicants arguments that the terms ---anticancer agent, tumors, parasitic or viral infection ---- in claims 15, 17 and 18 are definite. In regard to prior art

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rejection over Big's reference, the applicants state that the newly inserted proviso overcomes this reference. This is not true. The instant variable R3 can still represent OH or OCH₃ group and therefore, anticipates the instant claims. The examiner also does not agree with the applicants arguments regarding obviousness rejections. In regard to Dallavalle's reference, the applicants mention that publication date is June 2002. However, there was nothing in the article showing publication date of June 2002. In regard to Penco and Bom's reference, the substitution at 7th position is irrelevant. Bom teaches enhanced solution stability of 7-membered lactone ring as compared to 6-membered lactone ring in the camptothecin derivatives and therefore, provides the teaching and motivation to one skilled in the art to prepare the instant compounds by modifying compounds of Penco.

Conclusion

4. Rejection of claims 15, 17 and 18 under 35 U.S.C. 112, first paragraph is maintained for the reasons of record.
5. Rejection of claims 9, 15, 17 and 18 under 35 U.S.C. 112, second paragraph is maintained for the reasons of record.
6. Rejection of claims 1-3, 6, 7, 13 and 15-19 under 35 U.S.C. 102(b) is maintained for the reasons of record is maintained for the reasons of record.
7. Rejection of claims 1-4, 13 and 15-19 under 35 U.S.C. 103(a) is maintained for the reasons of record.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-9, 13 and 15-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In independent claim 1, the formulae (I) and (II) introduce new matter since they were not described in the specification as originally filed. In formula (I), -OH group is attached to lactone ring via a CH₂ group in the specification (see page 8) while it is directly attached to lactone ring in the instant claim 1. Similarly, in regard to formula (II), the specification discloses 5-membered lactone ring while the formula (II) in instant claim 1 lacks 5-membered lactone ring. Both the formulae are not legible also. Also, the applicants have put a new proviso in claim 1. This proviso also introduces new matter since it was not described in the original specification.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In claim 1, the proviso, when R1 and R2 are hydrogen, R2 is not –OH or –OCH3 is confusing and indefinite since the actual intent is not clear. When R2 is a H, then how R2 can be anything else besides H.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on (571)272-0670. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Charanjit S. Aulakh
Primary Examiner
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